

**REMARKS**

Claims 1-5 and 8-15 are pending in this application. Applicant elected the group of claims consisting of claims 1-5 and 8-15 following a restriction requirement by the Examiner, and withdrew claims 6, 7, and 16, without prejudice. Claims 1-5 and 8-15 were also variously rejected under 35 U.S.C. §112 and 35 U.S.C. §102 in the Office Action mailed June 9, 2005.

The amendments herein are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant expressly reserves the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicant has carefully considered the points raised in the Office Action and believes that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

**Discussion of Restriction Requirement**

Restriction has been required as between the following allegedly distinct groups of inventions:

Group I (claims 1-5 and 8-15): drawn to method and apparatus claims for analysis, classified in class 436, subclass 164;

Group II (claims 6-7): drawn to a rigid holder, classified in class 206; and

Group III (claim 16): drawn to a syringe, classified in class 422, subclass 100.

During a phone conference with the Examiner on June 6, 2005, Applicant elected Group I (claims 1-5 and 8-15), without traverse. Applicant expressly reserves his right under 35 U.S.C. §121 to file one or more divisional or continuation applications directed to the nonelected

subject matter during the pendency of this application, or one or more applications claiming priority from this application.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1-5 and 8-15 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses this rejection.

Claims 1, 8, 10, and 15

Claims 1, 8, and 15 were rejected for an alleged failure to fulfill their preamble because the preambles of these claims require analysis of the test device but do not provide any means or steps of analysis.

Both claims 8 and 15 explicitly recite means or steps of analysis. For example, claim 8 recites the limitation of “*analyzing* the digital image of said at least one test device so as to determine the presence or absence of at least one visual indicator on said at least one test device.” Claim 8 (emphasis added). Claim 15 recites the limitations of “*analyzing* the digital image of said at least one test device so as to determine the presence or absence of at least one visual indicator on said at least one test device” and “generating a report based on whether said at least one visual characteristic is present or absent.” Claim 15 (emphasis added). Applicant submits that because claims 8 and 15 both recite an analyzing step (and a report generating step based on the analysis step in claim 15), the claims fulfill their preambles and satisfy 35 U.S.C. §112, second paragraph.

While Applicant believes that claim 1 is definite as originally claimed, in the interests of expediting issuance of the pending application, Applicant has amended claim 1 to address the Examiner’s concerns. Amended claim 1 now recites the limitation “wherein said scanner scans the at least one test device to generate a digital image thereof and said digital imaging software performs an analysis of the digital image.” In light of the Examiner’s rejections of claims 1, 8, and 15, Applicant has similarly amended independent claim 10 to include a limitation of “wherein the digital imaging software analyzes the digital image.” Applicant respectfully submits that claims 1,

8, 10, and 15 satisfy 35 U.S.C. §112, second paragraph, as all of the claims now explicitly recite an “analysis” claim limitation.

#### Claims 3 and 12

Claims 3 and 12 were rejected for being vague and indefinite as to the structure intended by “off-the-shelf digital scanner.” While Applicant believes that the term “off-the-shelf digital scanner” satisfies the requirements of 35 U.S.C. §112, second paragraph, Applicant has amended claims 3 and 12 to expedite prosecution.

The Examiner indicated that the phrase “off-the-shelf” is confusing because it could imply most equipment purchased from a vendor, and thus does not limit the structure of the scanner. The patent application as filed clearly indicates that the phrase “off-the-shelf digital scanner” can comprises a general purpose scanner, such as a UMAX scanner, that is used with consumer-grade personal computers (like a Compaq Presario 1500 Notebook computer) for scanning documents, as opposed to complex and expensive custom optical measuring systems used in conventional systems specifically designed for analyzing test devices. *See* ¶¶ 3, 8, and 19 of the patent application.

However, to expedite prosecution, Applicant has replaced the term “standard off-the-shelf digital scanner” with “general purpose digital scanner” in both claims 3 and 12. Applicant respectfully submits that this amendment is supported by the specification as filed in at least paragraphs 3, 8, and 19, which delineate between expensive custom test scanners and general purpose scanners, such as UMAX scanners, which are intended for general use with personal computers. Therefore, Applicant submits that claims 3 and 12, as amended, are definite and the Examiner’s rejection has been overcome.

#### Claims 2, 4, 5, 9-11, 13, and 14

Claims 2, 4, 5, and 9 were not specifically addressed in the Examiner’s rejections under 35 U.S.C. §112, second paragraph, and were apparently rejected as dependent on rejected parent claims. Independent claim 10 and dependent claims 11, 13, and 14 had no articulated reason for rejection under 35 U.S.C. §112, second paragraph, and were apparently rejected for similar reasons

as claims 1, 8, and 15. In light of the foregoing amendments and remarks regarding claims 1, 3, 8, 10, 12, and 15, Applicant respectfully submits that the Examiner's rejections under 35 U.S.C. §112 for all of claims 1-5 and 8-15 have been overcome.

Rejection under 35 U.S.C. §102

Claims 1-5 and 8-15 were rejected under 35 U.S.C. §102 as allegedly being anticipated by Kinoshita *et al.* (U.S. Patent 5,817,526) or Howard *et al.* (U.S. Patent 5,408,535). Applicant respectfully traverses this rejection.

As a preliminary matter, Applicant points out that the Examiner has not specified which limitations of which claims are anticipated by Kinoshita *et al.* and Howard *et al.*, and accordingly, has not demonstrated that all claim limitations are taught or suggested by the prior art. Moreover, Applicant respectfully submits that both Kinoshita *et al.* and Howard *et al.* fail to teach all limitations of independent claims 1, 8, 10, and 15, as well as many additional limitations in dependent claims 2-5, 9, and 11-14.

Kinoshita *et al.* teach an apparatus for performing an agglutination immunoassay. The Examiner states that the claimed template is read on the driving means in Kinoshita *et al.* However, Applicant first notes that the claimed template of Applicant's invention holds one or more test devices for scanning and is *not* taught by the driving means of Kinoshita *et al.* Furthermore, Kinoshita *et al.*'s microtiter plate (10) directly holds test samples and, therefore, is itself a test device. It is not a template for holding one or more test devices, as recited in claims 1, 8, 10, and 15. Finally, Applicant notes that Kinoshita *et al.* fail to teach or suggest several novel aspects of the template of the present invention, such as fitting on a scanning surface, including one or more windows, and/or maintaining one or more test device in a fixed location. *See, e.g.*, Claim 1 ("wherein the template is configured to fit on a scanning surface of said scanner and includes at least one window ...") and "maintain the at least one test device in a fixed location during scanning of the at least one test device"; Claim 8 ("wherein the template includes at least one window configured to receive and hold a test device therein" and "defining at least one target area for scanning based on the location of said at least one window in said template when the template is

positioned on the scanning surface”); Claim 10 (“maintain the at least one test device in a fixed location during scanning”); Claim 15 (“wherein the template includes at least one window configured to receive and hold a test device therein” and “defining at least one target area for scanning based on the location of said at least one window in said template when the template is positioned on the scanning surface”).

Howard *et al.* teach a video test strip reader that uses a video imager or camera. The Examiner states that the reading field (14), upon which individual test strips are placed, reads on the claimed template. However, like Kinoshita *et al.*, Howard *et al.* fail to teach or suggest several novel aspects of the claimed template in the independent claims of the present invention. For example, the reading field (14) does not contemplate the use of windows as claimed in independent claims 1, 8, and 15 and discussed above for Kinoshita *et al.* Moreover, claim 10 is a means-plus-function claim and is limited to the corresponding structure and equivalents thereof as disclosed in the specification. Howard *et al.* does not disclose, teach, or suggest any structures or equivalents to the structures disclosed in the present specification. *See, e.g.*, ¶¶ 6, 7, and 19-22 of the patent application and figures 1, 2A, and 2B.

Applicant respectfully submits that in light of the above remarks demonstrating the novelty of independent claims 1, 8, 10, and 15 over Kinoshita *et al.* and Howard *et al.*, these claims are now in condition for allowance. Similarly, dependent claims 2-5, 9, and 11-14, which depend from claims 1, 8, 10 and 15, respectively, are also in condition for allowance.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and

authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 532812000200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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